SUPINE ERGOMETER LEG BRACE

Field of the Invention

The present invention relates to devices used in exercise stress tests, specifically, supine bike echocardiography beds used in echocardiography stress tests. In particular, the present device is a leg support for maintaining patient leg alignment during lateral tilting of a supine bike echocardiography bed.

Background of the Invention

A stress test, sometimes called a treadmill test or an exercise test, allows physicians to add exercise to an electrocardiogram (ECG) in order to determine how well the heart handles work. During exercise, the body undergoes stress, or work, and requires more oxygen. The body's pump, the heart, must pump more blood to the body to meet this oxygen demand. Exercise tests or stress tests allow the physician to better understand the impact of this work on the heart.

Echocardiography is an ultrasound examination of the heart. An echocardiogram is able to present a clear and more detailed image of the heart than is possible with ECG studies. Also, echocardiography is non-invasive, relatively easy to perform and avoids radiation exposure to the patient. Further, if Doppler echocardiography is performed, the speed and direction of blood flow within the heart can be determined.

When the echocardiogram is performed, the patient is undressed from the waist up and lies on their left side on an examination table. The echocardiography technician then places a transducer against the side of the left chest wall and sound waves are directed toward the heart. The sound waves are reflected from the body surfaces they contact and are received by the transducer and converted into electrical impulses which are used to generate a picture of the heart. To improve contact with the body, a gel similar to mineral oil is applied to the transducer to maintain close contact with the skin.

The above-described echocardiogram procedure also can be performed as the heart is placed under exercise or stress. Typically, to exercise the patient during the echocardiography procedure, the patient will be asked to walk on a treadmill to create stress on the heart. An alternative method of exercising the patient to produce stress on the heart is to use a supine bike echocardiography table. An example of a prior art supine bike echocardiography table is shown in Fig. 1. In Fig. 1, supine bike stress table 10 is comprised of carriage 12 which is made mobile by wheels 14. Carriage 12 supports elevating pedestal 16 which is connected frame 18 to which cushions 20, 26 are attached for patient comfort. Attached to foot end 24 of stress table 10 is ergometer 26 which operates much like an exercise bicycle.

Still referring to Fig. 1, in operation, supine bike table 10 is used by having a patent lie on cushions 20, 26 of table 10, and having the patient place their feet on either side of ergometer 26 and into foot holders 28. Footholders 28 are attached to pedal 52 which is connected to crank 30 of shaft 32 which rotates an adjustable fly

wheel within case 34 of ergometer 26. The fly wheel resistance and other operational characteristics of ergometer 26 are adjusted by ergometer control 36. When the patient is in position on table 10, the patient begins to pedal ergometer 26 just as one would a bicycle. After a time peddling ergometer 26, the patient will begin to show and feel the signs of this exercise, and the stress effects of this exercise will begin to be evident in the heart muscle. To view the effects of exercise on the heart muscle, the physician or sonographer must perform echocardiography upon the patient during exercise or within a short time of the cessation of exercise.

Performing stress echocardiography with supine bike stress table 10 is accomplished by using control wand 38 to activate tilt arm 40 on pedestal 16. Referring now to Fig. 6, tilt arm 40 causes a lateral tilting of table 10 about the longitudinal axis of frame 18. This tilting can position frame 18, and the patient resting thereon, at a lateral tilt angle of between zero and up to ninety degrees although most testing is performed at less than a forty degree angle. It should be appreciated that with a supine bike stress table, the patient can continue to exercise during the tilting of table 10. This allows acquisition of stress echocardiography data during peak exercise (or the period of peak ischemia) rather than during the period after exercise known as recovery which happens when a treadmill is used to induce exercise. This advantage of supine bike exercise over treadmill exercise will be further described hereinafter.

Again, referring to Fig. 1, as stress table 10 is laterally tilted to an angle of up to ninety degrees, the patient is supported from sliding off the incline table by shoulder brace 42 and hip strap 43 (Fig. 1). When stress table 10 has achieved the desired angle, the technician then releases latch 44 of drop panel 22 to place the drop panel in lowered position 46. With drop panel 22 in lowered position 46, the technician has direct access to the left side chest wall of the patient where the echocardiography transducer must be placed to be most closely positioned to the heart and to best observe the actions of the heart. As the transmitted sound from the transducer is reflected and received by the transducer, the actions of the beating heart can be observed on a monitor attached to the echocardiographic equipment, and the pictures are recorded digitally and/or on video tape for examination by a physician. Again, it should be appreciated that during this entire procedure, that is while table 10 is flat and while table 10 is being inclined and while the technician is performing the echocardiography, the patient can continue to exercise on supine bike table 10.

By contrast, if a treadmill is used for such stress echocardiograms, the patient must first exercise on the treadmill until a sufficient degree of exercise activity has been obtained and then the patient must be transferred to a horizontal position on a bed positioned on their left side and only then can the technician or sonographer perform the echocardiographic examination. It will be appreciated that during this transfer process, the patient is no longer exercising and, therefore, for a period of some time the patient's heart is entering the period known as recovery during which the heart rate and

the changes induced by exercise are being resolved or eliminated. The longer the heart is in the recovery period before the echocardiogram is performed the less relationship the echocardiogram has to true stress cardiac performance.

Another problem with the use of treadmills for exercise occurs when transferring the patient from the treadmill to the bed. This transfer must be performed while manipulating a substantial number of electrical leads which are attached to the patient's chest to allow monitoring of electrocardiographic changes in the heart. The need to manipulate these wires results in additional wasted time between cessation of exercise and performance of the echocardiogram.

In view of these problems associated with treadmill exercise it can be appreciated that supine bike echocardiography (SBE) is considered by many to be a superior means of exercising a patient for echocardiography. One researcher has determined that ischemic wall motion abnormalities at the time of echocardiographic imaging are more frequent and more extensive during supine bicycle echocardiography, which may increase the detection of coronary artery disease (CAD) and facilitate interpretation of ischemia. (See, Shamim-M. Badruddin et al., Supine Bicycle vs. Post-Treadmill Exercise Cardiography in the Detection of Myocardial Ischemia, Journal of the American College of Cardiology. Vol. 33, No. 6, 1999.)

As previously described, during SBE, the patient is laterally tilted while exercising to place the left side chest wall in a lowered position for performance of the echocardiogram. This, of course, places the reclining patient on an angle of up to

ninety degrees, while the patient is continuing to pedal the ergometer. Most patients upon whom echocardiography is being performed are not necessarily in the best of physical condition and, in fact, may be elderly patients who have lost substantial muscle mass in their legs. This reduction in physical strength can, at times, make it inconvenient or difficult for the patient to continue to pedal the ergometer while positioned in a lateral incline of an angle of up to ninety degrees. Referring now to Fig. 5 it can be appreciated that an ill or elderly patient, when positioned at such an angle, will find difficulty in maintaining their legs in anatomical position while table 10 is tilted. For example, the right leg will not remain in a parallel position with respect to ergometer case 34 as is indicated by Arrow A. Rather, the patient's right leg will tend to tilt inwardly along Arrow C and into a position indicated by Arrow B where the patient's leg and knee will bump against ergometer case 34. Similarly, the patient's left leg, or downward leg, will not stay parallel to case 34 as indicated by Arrow A, but will tend to rotate or fall away from case 34 along a line shown by Arrow C. This rotation of the patient's left leg into a position shown by Arrow B can place uncomfortable stress on the patient's hip, knee and ankle joints and prevent the patient from comfortably continuing to pedal ergometer 26.

Therefore, a need exists for a device to support the legs and knees of a patient exercising on an SBE table while the table is being inclined to allow performance of the echocardiography procedure. It will be appreciated that any such support must be freely movable in the generally circular motion being produced by the patient's feet on

the pedals of ergometer 26 and allow for comfortable, adjustable support of the legs during reasonably vigorous exercise.

Therefore, it is an object of the present invention to provide support for a patient's legs while on a SBE table when the table is laterally tilted.

It is another object of the present invention to provide a comfortable support for the legs while the patient is exercising during the tilting of an SBE table.

Another object of the present invention is to prevent the patient's right leg from impacting against the ergometer of a supine bike echocardiography table.

Yet another object of the present invention is to retain a patient's left leg in alignment with the pedal and crank of the ergometer of a supine bike echocardiography table while the table is being tilted laterally to an angle of up to approximately ninety degrees.

Another object of the present invention is that the leg supports be adjustable and quickly and easily removable so as to be comfortable for the patient and to avoid becoming an obstruction should a patient emergency situation arise during the performance of the stress echocardiogram.

Summary of the Invention

These objects and advantages and more are achieved in the present invention which comprises an adjustable support for capturing the leg of a patient, the support being attached to an extension rod which is attached to the ergometer shaft or crank or pedal and which connection allows complementary movement of the support and shaft with the movement of the ergometer shaft or crank or pedal as the patient exercises on the ergometer.

Alternatively, the objects are achieved by an embodiment of the present invention in which one end of an elastic or non-elastic cord is attached to the leg of the patient and the other end of the cord is attached to a support to prevent the patient's legs from moving out of anatomical position during tilting of the table.

Description of the Drawings

Preferred embodiments of the invention, illustrative of the best modes in which the applicant has contemplated applying the principles, are set forth in the following description and are shown in the drawings and are particularly and distinctly pointed out and set forth in the appended claims.

Fig. 1 is a side elevation view of a prior art supine bicycle stress echocardiography table;

Fig. 2 is a right side and foot end perspective view of the supine bicycle stress echocardiography table of Fig. 1 showing a patient on the table with the patient's legs inserted into the foot holders of the ergometer and with the present invention in place on the ergometer and capturing the leg of the patient;

Fig. 3 is a fragmentary perspective view of the right side only of Fig. 2 showing the capture of the patient's leg within the support of the present invention and the extension rod connecting the support of the pedal of the ergometer;

Fig. 4 is a perspective view of the left side of the device shown in Fig. 2 and showing the bearing connector attached to the left pedal of the ergometer into which the extension rod for the support of the present invention is attached;

Fig. 5 is a perspective view taken from the foot of the table shown in Fig. 1 and showing the bedframe in a lateral tilted position;

Fig. 6 is a rear and head end perspective view of the table of Fig. 1 showing the table in a tilted position;

Fig. 7 is an exploded, fragmentary view of the support rod and bearing of the present invention with a cotter pin shown in position for coupling the rod to the bearing; and

Fig. 8 is a foot end perspective view of a supine bicycle stress echocardiography table showing a patient on the table with the patient's legs inserted into the foot holders of the ergometer and with an alternative embodiment of the present invention which maintains the legs of the patient in anatomical position by use of support cords.

Description of the Preferred Embodiment

Referring to Fig. 4, the components comprising one embodiment of the present invention will be described. In Fig. 4, left leg 48 of the patient is shown with the patient's shoe 50 strapped into foot holder 28 which is attached to pedal foot support 52 of ergometer 26. Left leg 48 is captured within leg support or leg pad 54 of the present invention and secured thereto by strap 56. It will be appreciated that the containment of leg 48 within leg pad or support 54 by strap 56 is not an immobilizing containment, rather, it is a supportive connection to allow movement of leg 48 to operate pedal 52 and crank 30 of ergometer 26 while preventing leg 48 from uncomfortably falling away from ergometer 26 and from alignment with pedal foot support 52 when table 10 is laterally tilted as shown in Fig. 5. Leg support 54 is a generally oval pad that is positioned in the calf area of left leg 48 with strap 56 securing leg 48 to support 54 by the use of a hook and pad fastener such as VELCRO® or a buckle mechanism. Leg support is curved to conform to the general shape of the calf.

Leg support 54 is adjustably attached to a first end of rod 58 by connector 60. Connector 60 allows leg support 54 to be adjusted along the longitudinal axis of rod 58 to position leg support 54 in a comfortable and supportive location on leg 48. A second end of rod 58 is inserted into receiver 62 and held in receiver 62 by cotter pin 64 which is inserted through aligned voids in receiver 62 and rod 58. In a preferred embodiment of the present invention, receiver 62 is connected to bearing

66 which in the preferred embodiment shown in Fig. 4 connects pedal arm 68 to crank 30 by threaded arm 82. Pedal arm 68 has pedal foot support 52 attached thereto.

It will be appreciated by those skilled in the art that alternative embodiments can be devised which provide an alternative connection between rod 58 and the crank assembly of the bicycle. The crank assembly includes, generally, pedal arm 68 and crank 30 and shaft 32 (Fig. 1) of bicycle or ergometer 26. Pedal arm 68 and crank 30 and shaft 32 form the cranking mechanism of ergometer 26 and each can serve as a means of connection or a point of connection for rod 58 in providing a supportive connection of leg support 54 to the cranking mechanism of ergometer 26. The object of the alternative connection is to permit leg support 54 and rod 58 to move in conjunction with the cranking apparatus of ergometer 26 which is comprised of pedal arm 68 and/or crank 30 and/or shaft 32. For example, crank 30 could have an arm attached to crank 30 which parallels arm 68 and to which a bearing and receiver, similar to bearing 66 and receiver 62 of the present invention, could be attached. This would allow attachment of rod 58 to crank 30. In yet another alternative embodiment, an extension to shaft 32 (Fig. 1) could be placed on ergometer 26 which would extend beyond crank 30 to allow attachment of rod 58 to shaft 32 via a suitable rotational bearing with rod 58 being allowed to travel in connector leg which would rotate with respect to support 54. Alternatively, a cam could be attached to crank 30 and rod 58 could follow the cam, while secured

therein, to account for the movement of rod 58 with respect to crank 30. Therefore, it will be appreciated that the preferred embodiment illustrated herein is not a limitation upon the construction on the present invention, but rather, is illustrative of the best mode of which the inventor is presently aware.

Referring now to Fig. 2, the positioning of a patient 70 on pad 26 of frame 18 of table 10 is shown. Left leg 48 is shown in place in pedal support 52 which is on the left side of case 34 of ergometer 26 and right leg 72 is within pedal foot support 52 which is on the right side of case 34 of ergometer 26.

Referring now to Fig. 3, right leg 72 of a patient is shown secured within leg support 54 by strap 56. By examination of Figs. 2, 3 and 4 it can be understood that when supine bike stress table 10 is in its horizontal position that a patient is able to operate ergometer 26 without either of legs 48, 72 contacting case 34. However, when supine bike table 10 is laterally tilted, as is shown in Fig. 5, it will be appreciated that, in the absence of the present invention, right leg 72 would tend to respond to gravity, and strike or rub against case 34. Likewise, left leg 48 would tend to fall away from case 34 and require substantial patient effort to maintain anatomical position of their leg or, that is, the straight alignment of legs 48, 72 with pedal foot supports 52 of ergometer 26.

Still referring to Fig. 5 supine bike stress table 10 is shown in a laterally tilted position, the tilt being a rotation about the longitudinal axis of table 10. When a patient is in position on table 10 and the legs of the patient are in position with the

feet captured within foot supports 52 the force of gravity will tend to move the legs and knees in particular, out of anatomical position which is a generally perpendicular alignment with frame 18 of table 10 as represented by Arrows A extending from foot supports 52. The force of gravity will tend to cause movement of the legs in the direction of Arrow C and ultimately force the legs into an angled alignment with respect to frame 18 which is represented by Arrows B. When the legs of the patient have given way to the force of gravity and are forced into an alignment indicated by Arrow B, it can be appreciated that the patient's right leg, or upper leg, will tend to strike against cover 34 of ergometer 26 and the left leg, or lower leg, will tend to fall away from cover 34 of ergometer 26 with only the patient's strength to serve as a support for the left leg. As previously stated this rotation of the left leg can cause substantial stress on the patient's hip, upper leg, and knee and prevent the patient's ability to engage in useful exercise while on supine bike stress table 10 when it is in the laterally angled position of Fig. 5.

The present invention avoids this problem by supportively maintaining anatomical position and a straight alignment between legs 48, 72 of patient 70 and the ergometer cranking apparatus comprised of pedal arm 68, crank 30 and shaft 32 by maintaining legs 48, 72 directly in line with foot support 52. In this manner, the patient does not need to expend any effort or energy to prevent their legs 48, 72 from striking case 34 or falling away from case 34 and can comfortably devote their effort to peddling ergometer 26 to maintain the proper exercise levels for

echocardiography.

Referring now to Fig. 7 a more detailed examination of the construction and assembly of rod 58, cotter pin 64 and bearing 66. In general, rod 58 is inserted into receiver portion 62 of bearing 66. Rod 58 is then secured within receiver 62 by the insertion of cotter pin 64 into aligned voids 63a 63b of rod 58 and receiver 62. In the present embodiment, it can be seen that receiver 62 is of unitary construction with housing 80 which encloses bearing 66. Bearing 66 is, in a preferred embodiment, attached to crank 30 of ergometer 26 by screwing threaded arm 82 into the threaded void of crank 30 which normally is used to receive pedal arm 68 (Fig. 4). After threaded arm 82 has been threaded by hand into crank 30 secured attachment is accomplished by tightening threaded arm 82 into crank 30 through use of hexhead 84. This securely attaches bearing 66 crank 30. Once bearing 66 is mounted on crank 30, pedal arm 68 holding pedal 52 can be inserted into threaded void 86 of bearing 66 and securely tightened. The result of this assembly can be seen in Fig. 4 wherein bearing 66 is attached to crank 30 and pedal arm 68 is inserted into void 86 of bearing 66. This preferred embodiment allows full rotation of pedal 52 about pedal arm 68 and allows internal bearings contained in housing 80 of bearing 66 to allow rotation of threaded arm 82 as crank 30 is pedaled by a patient. This construction also allows rod 58 to rotate about pedal arm 68 and crank 30 without causing any movement or rubbing of leg support 54 against the patient's leg.

Referring now to Fig. 8, an alternative embodiment of the present invention is

presented wherein the legs of the patient are prevented from being forced out of anatomical position with respect to pedals 52 during the tilting of table 10 by the use of cords or elastic cords which are connected between leg cuff or strap 90a, 90b which encircles the patient's leg and which is attached to either case 34 or an upright support 82 which is attached to frame 18. More specifically, a upright support 82 is attached to the side of frame 18 which is to be elevated. A connector 84a attaches cord 86a to securing rod 82. A second connector 88a attaches cord 86a to leg cuff 90a. A similar connection is made for the patient's left leg, however, cord 86b is secured to case 34 rather than a separate securing rod 82. It will be appreciated that a second securing rod 82 could be employed approximate to case 34 for holding cord 86b. As frame 18 is tilted by tilt arm 40 on pedestal 16, cords 86a, 86b hold the patient's legs in anatomical position with respect to pedals 52 and to prevent the patient's right leg from hitting against case 34 and to prevent the patient's left leg from falling away from case 34 and placing an uncomfortable strain on the patient's knee and hip joint.

As required, detailed embodiments of the present inventions are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention, which may be embodied in various forms. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention in virtually

any appropriately detailed structure.

In the foregoing description, certain terms have been used for brevity, clearness and understanding; but no unnecessary limitations are to be implied therefrom beyond the requirements of the prior art, because such terms are used for descriptive purposes and are intended to be broadly construed. Moreover, the description and illustration of the inventions is by way of example, and the scope of the inventions is not limited to the exact details shown or described.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the scope of the invention which, as a matter of language, might be said to fall there between.